



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/126,096	07/30/1998	EUGENE D. THORSETT	002010-137	8518

21839 7590 02/04/2003

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/126,096

Applicant(s)
Thorsett et al.

Examiner
Deepak Rao

Art Unit
1624



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 26, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 10, 12, 13, and 15-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 10, 12, 13, and 15-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1624

DETAILED ACTION

This office action is in response to the amendment filed on November 26, 2002.

Claims 1-4, 7, 10, 12-13 and 15-22 are pending in this application.

The following rejections are withdrawn:

1. The rejections under 35 U.S.C. 112, second paragraph of the previous office action are withdrawn in view of the amendments, which are sufficient to overcome the rejections.
2. The rejection under 35 U.S.C. 102(e) and 102(e)/103(a) of the previous office action are withdrawn in view of the amendments, which eliminate the possibility of biaryl compounds from the definition of R⁵. The reference does not teach or fairly suggest compounds having other than a biaryl group at that position.

The following rejection is maintained:

Claims 1-4, 7, 10, 12, 13 and 15-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of U.S. Patent No. 6,492,421 (S.No. 09/126,095), for the reasons provided in the previous office action which are incorporated here by reference. The reference claims are drawn to compounds of formula I wherein R² and R³ together form a heterocyclic ring. The instantly claimed compounds differ from the reference compounds by having a substituent R⁴ (which can be methyl) at the 2-position of the ring formed by R² and R³, and thus, differ by a -CH₂ group and are therefore,

Art Unit: 1624

structural homologs of the reference compounds. The reference compounds are also taught to have pharmaceutical therapeutic activity related to VLA-4, and therefore, sufficient motivation exists for one of ordinary skill in the art to prepare the homologous compounds, i.e., compounds that differ by e.g., a methyl substituent.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant cites *In re Coes* and *In re Langer* and argues that "the mere fact that there is "homology" should not automatically be equated with *prima facie* obviousness". However, contrary to applicant's arguments, the *Coes* court ruled that "[A]djacent homologues of old substances are unpatentable as new compounds particularly where the homologues are not markedly superior to the old substances". On the other hand, the *Langer* case is with respect to sterically hindered amines as opposed to unhindered amines, and thus, the facts are remote from the instant case. *Lalu* is not on point for the instant situation because the case scenario in *Lalu* was between claimed products vs. prior art disclosed intermediate compounds and therefore, it was concluded that 'the prior art does not provide motivation to stop the reference synthesis to investigate the intermediate compounds with the expectation of arriving at the claimed products'.

In fact, the prior art structures do not even have to be true homologs to establish *prima facie* case of obviousness: "Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain

Art Unit: 1624

compounds with improved properties.” See *In re Deuel*, 51 F.3d 1558, 34 USPQ 2d 1214 (Fed. Cir. 1995). In the instant case the reference compounds and the instantly claimed compounds are disclosed to have similar pharmaceutical therapeutic activity, which provides sufficient motivation to one of ordinary skill in the art to prepare the compounds having an alkyl (e.g., methyl) substituent on the ring in place of the hydrogen of the reference compounds.

For all the above reasons, the obviousness-type double patenting rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

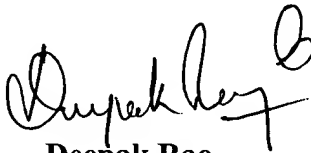
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

Art Unit: 1624

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Deepak Rao
Primary Examiner
Art Unit 1624

February 1, 2003